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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,495

06/26/2006

Franz-Christoph Bange

770036.402USPC

7732

500 7590 06/08/2009

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

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SUITE 5400

SEATTLE, WA 98104

EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

06/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,495	Applicant(s) BANGE, FRANZ-CHRISTOPH	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 19-27, 31-44 and 46-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 19-27, 31-44 and 46-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's Response to Office Action, received 27 February 2009, is acknowledged. Claims 1, 2, 4, 9, 10, 19, 20, 21, 22, 23, 24, 25, 26, 27, 31, 32, 33, 34, 36, 37, 38, 39, 43, 46, 47, 48, 49 and 50 have been amended. Claims 12-17, 28 and 45 have been cancelled. New claims 52-54 have been added.
2. Claims 1-11, 19-27, 31-44 and 46-54 are pending and under consideration.

Rejections/Objections Withdrawn or Moot

3. The objection to claim 28 is moot in light of the cancellation of the claim.
4. The rejection of claim 28 under 35 U.S.C. 102(b) as being anticipated by Fleischmann et al (U.S. Pat. No. 6,294,328, 25 September 2001) is moot in light of the cancellation of the claim.
5. The objection to Figures 1-5 because the wording is in German, is withdrawn in light of the submitted replacement figures.
6. The objection to claim 2 is withdrawn in light of the amendment of the claim.
7. The objection to claim 4 is withdrawn in light of the amendment of the claim.
8. The objection to claim 9 is withdrawn in light of the amendment of the claim.
9. The objection to claim 19 is withdrawn in light of the amendment of the claim.
10. The objection to claim 20 is withdrawn in light of the amendment of the claim.
11. The objection to claim 21 is withdrawn in light of the amendment of the claim.
12. The objection to claim 22 is withdrawn in light of the amendment of the claim.
13. The objection to claim 23 is withdrawn in light of the amendment of the claim.
14. The objection to claim 24 is withdrawn in light of the amendment of the claim.
15. The objection to claim 25 is withdrawn in light of the amendment of the claim.
16. The objection to claim 26 is withdrawn in light of the amendment of the claim.

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17. The objection to claim 27 is withdrawn in light of the amendment of the claim.
18. The objection to claim 31 is withdrawn in light of the amendment of the claim.
19. The objection to claim 33 is withdrawn in light of the amendment of the claim.
20. The objection to claim 36 is withdrawn in light of the amendment of the claim.
21. The objection to claim 37 is withdrawn.
22. The objection to claim 39 is withdrawn in light of the amendment of the claim.
23. The objection to claim 43 is withdrawn in light of the amendment of the claim.
24. The objection to claim 46 is withdrawn in light of the amendment of the claim.
25. The objection to claim 47 is withdrawn in light of the amendment of the claim.
26. The objection to claim 50 is withdrawn in light of the amendment of the claim.
27. The rejection of claims 36-44 and 51 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of applicants' arguments.
28. The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being indefinite for "the other probe", is withdrawn in light of the amendment of the claims.
29. The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being indefinite for "the other probe", is withdrawn in light of the amendment of the claims.

Rejections Maintained

30. The rejection of claims 1-11 under 35 U.S.C. 112, second paragraph, as being indefinite for determination of a "negative result", is maintained.

Applicants argue that the amendment of the claims obviates the rejection.

The examiner has considered applicants' argument in light of the amendment of the claims, but does not find it persuasive. While the amendment does clarify the metes and bounds of what is amplified, step b recites that one determines the presence or absence of the

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"polymorphism specific for *M. tuberculosis* in position -215". However, the claim does not recite what this polymorphism is. Thus, it remains unclear how one determines a negative result, or a positive result.

Claim Rejections - 35 USC § 112

31. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

32. Claims 19-27, 31-44 and 46-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to probes or methods for detecting the polymorphism specific for *M. tuberculosis* located in position -215.

It is unclear what is the polymorphism because none of the claims recites what is considered the specific *M. tuberculosis* polymorphism.

33. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is directed to a kit further comprising reagents necessary or useful for carrying out a nucleic acid amplification or detection reaction. It is unclear what reagents may or may not be considered "useful".

Conclusion

34. No claims are allowed.

35. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

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272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

June 8, 2009